

Exhibit 1

**IN THE UNITED STATES DISTRICT COURT FOR THE
NORTHERN DISTRICT OF FLORIDA
PENSACOLA DIVISION**

IN RE: ABILIFY (ARIPIRAZOLE)
PRODUCTS LIABILITY LITIGATION,

Case No. 3:16-md-2734

Judge M. Casey Rodgers
Magistrate Judge Gary R. Jones

This Document Relates to:

Ellen J. Hutt, et al.
Case No. 3:17-cv-634

ORDER

Pending before the Court is Plaintiffs' Memorandum in Support of Dr. David Kessler Testifying as an Expert Witness, which the Court construes as a motion to take Dr. Kessler's deposition. ECF No. 37. Defendants have filed a response in opposition. ECF No. 38.

Upon consideration, Plaintiffs' motion is due to be **DENIED**. Plaintiffs ask this Court—after the discovery deadline—for leave to take a deposition of her own retained expert (Dr. Kessler) in the event he is unable to testify at trial because “reports have been circulating in the media about his potential role within” President-Elect Joe Biden's administration. To describe the issue is nearly to decide it, but, put simply, Plaintiffs do not demonstrate good cause and excusable neglect to modify the Court's scheduling order to allow for this belated deposition. Plaintiffs were aware

of the circumstances giving rise to the instant motion in advance of the discovery deadline and failed to promptly act, the asserted need to depose Dr. Kessler rests entirely on speculation as to his future employment by the federal government, and, in any event, a deposition to preserve Dr. Kessler's testimony for trial would not avoid the regulations prohibiting government employees from testifying in private litigation.

I. BACKGROUND

This is a products liability action against Defendants Bristol-Myers Squibb Co., Otsuka America Pharmaceutical, Inc., and Otsuka Pharmaceutical Co., Ltd., concerning Samantha Hutt's use of the atypical antipsychotic drug Aripiprazole, commonly known by its trade name "Abilify." ECF No. 1. This case was consolidated in multidistrict litigation for the coordination of pretrial proceedings. 28 U.S.C. § 1407. Plaintiffs were eligible to participate in the MDL settlement program established by the parties but elected to continue litigating their claims on an individual basis. ECF No. 8. Plaintiffs, however, have advised the Court that they do not waive venue in the District of Massachusetts, so this case will be remanded there for trial. ECF No. 10; see *also Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26 (1998).

In April 2018, Plaintiffs identified Dr. Kessler as a “general expert” on “the regulatory aspects related to drugs in the United States and more specifically the regulatory history of Abilify and the regulations applicable to” Defendants. ECF No. 37 at 1. Dr. Kessler, a doctor and lawyer who served as Commissioner for the Food and Drug Administration from 1990 to 1997, has “authored a number of articles in legal, medical[,] and scientific journals related to FDA regulations of drugs and medical devices.” *Id.* at 2. Moreover, during his tenure as FDA Commissioner, Dr. Kessler was responsible for overseeing the Center for Drug Evaluation and Research, the Center for Devices and Radiological Health, and the Center for Biologics Evaluation and Research. *Id.*

Defendants have pressed Plaintiffs to produce Dr. Kessler for a discovery deposition since June 2020. ECF No. 38-1. On July 24, Defendants noticed Dr. Kessler for a videotaped deposition to take place on August 28. ECF No. 38-3. Counsel for the individual plaintiffs, including in this case, resisted, but the Court overruled their objections at a hearing on August 7, 2020. MDL ECF No. 1290.¹ Nevertheless, the parties agreed to stay Dr. Kessler’s deposition pending mediation. ECF No. 38 at 7.

¹ Citations in this order to “MDL ECF No. ____” refer to the docket for the MDL, Case No. 3:16-md-2734-MCR-GRJ (N.D. Fla.), rather than the docket for this individual case.

On October 5, following unsuccessful mediation, Defendants inquired into the availability of the fact and expert witnesses in the Court's five "fast-track cases," including this case and Dr. Kessler. ECF No. 38-4. At a status conference on October 13, and in an order memorializing the status conference, the Court entered a scheduling order that included a discovery deadline of December 18, 2020, as well as a January 8, 2021, deadline for the filing of dispositive and *Daubert* motions. ECF No. 1305 at 2. On October 19, when Plaintiffs failed to respond to Defendants' October 5 inquiry, ECF No. 38 at 8, and in view of the Court's scheduling order, Defendants noticed Dr. Kessler for a deposition to take place on December 18, ECF No. 38-4.

On November 7, media outlets projected Joe Biden as the winner of the 2020 Presidential Election. *Biden Defeats Trump for White House*, The Associated Press (Nov. 7, 2020), <https://apnews.com/article/joe-biden-wins-white-house-ap-fd58df73aa677acb74fce2a69adb71f9>. Two days later, President-Elect Biden publicly named Dr. Kessler as a co-chair of a health and science task force to address the COVID-19 pandemic. *Members of President-Elect Biden's Coronavirus Task Force*, The Associated Press (Nov. 9, 2020), <https://apnews.com/article/members-biden-coronavirus-task-force-319dee82242fe00091cdf98b8f5df29a>.

One week later, on November 16, counsel for other “fast-track” plaintiffs notified Defendants that Dr. Kessler was unavailable for a deposition on “December 15[,]” but she would work to find another date. ECF No. 38-6 at 2. On December 1, that same counsel advised Defendants that Dr. Kessler was also unavailable on December 18 but could attend a deposition on December 29. ECF No. 38-7. The next day, Bloomberg News reported that President-Elect Biden was considering appointing Dr. Kessler as FDA Commissioner. ECF No. 37 at 11–15.

Plaintiffs did not follow up with Defendants until more than two weeks later, on December 17. ECF No. 38-9. Plaintiffs informed Defendants that Dr. Kessler’s availability was “extremely limited” and “[i]n light of his upcoming unavailability, [they] intended to notice a trial preservation deposition on December 30.” *Id.* at 2. Plaintiffs offered Dr. Kessler for a discovery deposition by Defendants to take place on December 28 or 29. *Id.*

The parties did not advise the Court of this discovery dispute until December 21. The Court held a telephonic hearing the following day, at which Defendants raised the issue of precluding Plaintiffs from tendering

Dr. Kessler as a “general expert” at trial should he become a federal government employee.² The Court directed briefing by the parties.

II. LEGAL STANDARD

Plaintiffs’ motion implicates the Court’s scheduling order, ECF No. 1305, because the current version of the Federal Rules of Civil Procedure does not distinguish between discovery depositions and depositions to preserve a witness’s testimony for trial (“*de bene esse*” depositions). *Smith v. Royal Caribbean Cruises, Ltd.*, 302 F.R.D. 688, 689–93 (S.D. Fla. 2014) (citing *Chrysler Int’l Corp. v. Chemaly*, 280 F.3d 1358 (11th Cir. 2002)); see also *DeBose v. Univ. of S. Fla. Bd. of Trustees*, No. 8:15-cv-2787-EAK-AEP, 2018 WL 8918978, at **1–2 (M.D. Fla. May 18, 2018); *Layton v. Mentor Worldwide LLC*, No. 1:16-cv-161-MP-GRJ, 2016 WL 9136965, at *1 (N.D. Fla. Oct. 19, 2016). Accordingly, a party “engaged in standard civil litigation, represented by counsel, in a routine civil case like those pending in every court in the country, has no right to take a trial deposition of any witness contrary to the schedule set forth by the Court’s Rule 16 scheduling orders.” *Smith*, 302 F.R.D. at 693.

² To be clear, Defendants did not move to compel Dr. Kessler’s deposition and have not filed a motion to extend the discovery deadline to take his deposition.

“A party seeking the extension of an already-expired scheduling order deadline must show both good cause and excusable neglect.” *Payne v. C.R. Bard, Inc.*, 606 F. App’x 940, 944 (11th Cir. 2015) (citing Fed. R. Civ. P. 6(b)(1), 16(b)(4)). “To establish good cause the party seeking the extension must establish that the schedule could not be met despite the party’s diligence.” *Ashmore v. Sec’y, Dep’t of Transp.*, 503 F. App’x 683, 685 (11th Cir. 2013). The Supreme Court has described “excusable neglect” as an “elastic concept,” whereby the Court must take into account all of the relevant circumstances, including “the danger of prejudice to the [nonmovant], the length of the delay and its potential impact on judicial proceedings, the reason for the delay, including whether it was within the reasonable control of the movant, and whether the movant acted in good faith.” *Pioneer Inv. Servs. Co. v. Brunswick Assocs. Ltd. P’ship*, 507 U.S. 380, 392–95 (1993).

III. DISCUSSION

Plaintiffs ask the Court to order Dr. Kessler’s deposition “proceed expeditiously and that Plaintiffs be permitted to preserve his testimony in the event that he will be unavailable at trial.” ECF No. 37 at 1. Plaintiffs argue that federal statutes and regulations would not preclude Dr. Kessler from testifying at trial as an expert witness *but* that a deposition to preserve

his testimony is necessary because he “may later be unavailable due to scheduling conflicts[] or other agency related needs” arising from his role as co-chair of President-Elect Biden’s COVID-19 Task Force or a “higher appointment” within the administration. *Id.* at 6–8.

Plaintiffs, however, fail to demonstrate good cause and excusable neglect to modify the Court’s scheduling order to allow for this belated deposition. For starters, Plaintiffs’ motion makes no mention of its burden. Although this silence speaks volumes, the Court concludes, based on its own review of the relevant record, that Plaintiffs have not acted diligently. Plaintiffs knew in November that Dr. Kessler’s availability was an issue, ECF No. 38-6 at 2, but they did not file a motion to extend the discovery deadline. What’s more, Plaintiffs concede they knew on December 2 that they had reason to believe Dr. Kessler may be unavailable for trial (because President-Elect Biden could appoint him to a permanent government position). ECF No. 37 at 11–15. Yet, Plaintiffs waited two weeks, until the day before the discovery deadline, to notify Defendants that they wanted to take a deposition to preserve his testimony for trial, ECF No. 38-9, but, in doing so, let the discovery deadline lapse without explanation.

If Dr. Kessler's testimony were as important as Plaintiffs represent it is, ECF No. 37 at 8, it should have been a priority. The Eleventh Circuit has warned "parties who delay in taking a needed deposition and who assume that a district court will draw (when the Rules do not and if the pretrial order does not) a distinction, for pretrial scheduling purposes, between different kinds of depositions" that they "assume a risk: they cannot count on the trial court's allowing a deposition to be taken closer to the trial date." *Chrysler Int'l Corp.*, 280 F.3d at 1362 n.8. So too here. "This is not a case where Plaintiffs expected [Dr. Kessler] to provide trial testimony but [Dr. Kessler] later became unavailable for an unforeseen reason." *Dopson-Troutt v. Novartis Pharm. Corp.*, No. 8:06-cv-1708-T-24-EAJ, 2013 WL 5231413, at *2 (M.D. Fla. Sept. 16, 2013). Plaintiffs had plenty of notice that Dr. Kessler's deposition would not take place during the discovery period, but they failed to act diligently. Therefore, Plaintiffs will not be granted an exception from the deadlines in the Court's scheduling order.

The thrust of Plaintiffs' motion also rests on untenable speculation about Dr. Kessler's availability. Plaintiffs' suggestion that Dr. Kessler will be unavailable to testify at trial because he is a government employee is

based on a news article that has already proven false in other respects.³

This is not sufficient for this Court to conclude that the trial court will find Dr. Kessler, Plaintiffs' own expert, unavailable to testify at trial so that his deposition may be used in Plaintiffs' case-in-chief. *See Kamara v. United States*, No. 04-CIV-626(THK), 2005 WL 2298176, at *6 (S.D.N.Y. Sept. 20, 2005) ("[B]ecause Dr. Liebowitz has been retained as Plaintiffs' expert, an even greater showing than mere unavailability is required to excuse his attendance at trial."). Nevertheless, if this speculation comes to fruition—and President-Elect Biden nominates Dr. Kessler to, once again, lead the FDA—there is no telling when that nomination will occur and how long it will take the Senate to act on the nomination. Dr. Kessler may still be available to testify when this case is set for trial in Massachusetts.

Lastly, assuming Dr. Kessler is a government employee at the time of trial, Plaintiffs cite no authority—and the Court is aware of none—for the proposition that regulations concerning the testimony of government

³ The article attached to Plaintiffs' motion states that President-Elect Biden would likely nominate New Mexico Governor Michelle Lujan Grisham or former Surgeon General Vivek Murthy to be Secretary of the Department of Health and Human Services. ECF No. 37 at 11–15. Five days later, President-Elect Biden announced his intent to nominate California Attorney General Xavier Becerra to that position. *Biden Picks Xavier Becerra to lead HHS, Coronavirus Response*, The Associate Press (Dec. 7, 2020), <https://apnews.com/article/joe-biden-pandemics-coronavirus-pandemic-xavier-becerra-harvard-bc89947ff5ad8d21bc272743607d01fa>.

employees do not apply to deposition testimony used at trial. Although there is some dispute as to whether Dr. Kessler's testimony would be barred under 5 C.F.R. § 2635.805, Dr. Kessler would be subject to the Housekeeping Statute (5 U.S.C. § 301) and a federal agency's *Touhy*⁴ regulations. *Westchester Gen. Hosp., Inc. v. Dep't of Health and Human Servs.*, 443 F. App'x 407, 409 n.1 (11th Cir. 2011); *Moore v. Armour Pharm. Co.*, 927 F.2d 1194, 1197 (11th Cir. 1991). For instance, the FDA maintains its own *Touhy* regulations, which prohibits officers and employees from testifying "to any function of the Food and Drug Administrative" without approval of the FDA Commissioner. 21 C.F.R. § 20.1(a). Moreover, federal employees are prohibited from "engag[ing] in outside employment or any other outside activity that conflicts with his official duties." 5 C.F.R. § 2635.802. Plaintiffs cannot circumvent these regulations by deposing Dr. Kessler now because that testimony can only be used at trial as if Dr. Kessler were testifying live, with all attendant circumstances. Fed. R. Civ. P. 32(a)(1)(B).

In sum, Plaintiffs' motion presents two hypotheticals, but neither warrants extending the discovery deadline to take Dr. Kessler's deposition. If Dr. Kessler is a government employee, Plaintiffs' proposed deposition

⁴ *United States ex rel. Touhy v. Ragen*, 340 U.S. 462 (1951).

would not circumvent the pertinent regulations prohibiting his trial testimony. If Dr. Kessler is not a government employee, he should be available to testify at trial. Therefore, Plaintiffs' motion is due to be denied.

IV. CONCLUSION

Accordingly, it is **ORDERED** that Plaintiffs' motion to take Dr. Kessler's deposition, ECF No. 37, is **DENIED**.⁵

DONE AND ORDERED this 5th day of January 2021.

s/ Gary R. Jones
GARY R. JONES
United States Magistrate Judge

⁵ The motion also was filed in the MDL proceedings 3:16-md-2734-MCR-GRJ at ECF No. 1312 and therefore this order will be filed in the MDL case.